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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/488,867	01/21/2000	Michael J. Imperiale	11203-002001	5039

20985 7590 06/12/2003

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EXAMINER

WHITEMAN, BRIAN A

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 06/12/2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/488,867

Applicant(s)

IMPERIALE, MICHAEL J.

Examiner

Brian Whiteman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/3/02.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13, 14, 17-27, 31-35, and 40-42 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

- 5) ☒ Claim(s) 1,3-5,18,20,21,23-25,31-35,40 and 41 is/are allowed.

- 6) ☒ Claim(s) 2,9,10,11,13,14,19,26,27 and 42 is/are rejected.

- 7) ☒ Claim(s) 6-8,17,22 is/are objected to.

- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.

- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some * c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.

4) ☐ Interview Summary (PTO-413) Paper No(s). _____.

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

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DETAILED ACTION

Non-Final Rejection

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/3/03 has been entered.

Claims 1-11, 13, 14, 17-27, 31-35, and 40-42 are pending.

Applicant's traversal, the amendment to claims 1, 13, 17, 19, 27, 31, 32, 33, 40, 41, and 42 in paper no. 22 is acknowledged and considered.

Claim Objections

Claims 6-8 are objected to because of the following informalities: a nucleic acid does not produce a non-functional adenovirus capsid protein. A nucleic acid can encode a non-functional adenovirus capsid protein.

Claim 17 is objected because of the following informality: remove the underline “1” on the last line after the term “gene”.

Claim 22 is objected to because of the following informalities: a nucleic acid does not produce a capsid protein. A nucleic acid can encode an adenoviral capsid protein.

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Claim 27 is objected because of the following informality: the phrase "a vector system of claim 1, claim 17, claim 18, or claim 19" in claim 27 is in improper format for a dependent claim. Suggest replacing the phrase with -- the vector system of claim 1, claim 17, claim 18, or claim 19 --.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9 and 42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims read on a vector system comprising: 5' and 3' viral inverted terminal repeats (ITRs). The specification provides sufficient description of adenovirus 5' and 3' ITRs. See page 12, lines 13-20. However, viral ITRs embrace AAV ITRs and the specification does not disclose AAV ITRs. The specification does not provide sufficient description of a genus of viral terminal repeat.

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The court in Enzo 188 F.3d at 1374, 52 USPQ2d at 1138 states:

It is well settled that patent applications are not required to disclose every species encompassed by their claims, even in an unpredictable art. However, there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and use the invention as broadly as it is claimed.

In re Vaeck, 947 F.2d 48, 496 & n.23, 30 USPQ2d 1438, 1445 & n.23 (Fed. Cir. 1991)(citation omitted). Here, however, the teachings set forth in the specification provide no more than a “plan” or “invitation” for those of skill in the art to experiment...; they do not provide sufficient guidance or specificity as to how to execute that plan. See Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993); In re Wright, 999 F.2d...[1557], 1562, 27 USPQ2d...[1510], 1514. [footnote omitted].

Thus, the specification does not describe the claimed invention in such a way as to reasonably convey to one skilled in the art that inventor, at the time the application was filed, had possession of the claimed invention.

Applicant's arguments with respect to claims 9 and 42 have been considered but are moot in view of the new ground(s) of rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 2, 10, 11, 13, 14, 19, and 26-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites the limitation “adenovirus capsid, packaging, and 52/55 kDa protein encoding sequences” on line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 1 does not recite protein encoding sequences.

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In addition, the limitation "packaging...protein" is not defined by the claim. Claim 1 recites an adenovirus serotype-specific cis-packaging sequence in part a) and in part b) and does not recite a packaging protein encoding sequence.

Applicant's arguments with respect to claim 2 have been considered but are moot in view of the new ground(s) of rejection.

Claims 10 and 11 recite the limitation "the failure to produce a functional 52/55 kDa trans-acting protein" on lines 1-2. There is insufficient antecedent basis for this limitation in the claim. Suggest amending the claim to read -- failure to encode a functional 52/55kDa trans-acting protein --.

Applicant's arguments with respect to claims 10 and 11 have been considered but are moot in view of the new ground(s) of rejection.

Claims 13 and 14 recite the limitation "the helper-dependent adenovirus" on line 2. There is insufficient antecedent basis for this limitation in the claims. ^{Also,} It is unclear whether the limitation of claim 13 limits the origin of the protein in the system of claim 1 or if the cell is part of the system.

Applicant's arguments with respect to claims 13 and 14 have been considered but are moot in view of the new ground(s) of rejection.

Claims 19 and 26-27 recite the limitation "the helper adenovirus" on line 11. There is insufficient antecedent basis for this limitation in the claims.

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Applicant's arguments with respect to claims 19 and 26-27 have been considered but are moot in view of the new ground(s) of rejection.

Regarding claim 27, the word "means" is preceded by the word(s) "carrier" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967).

Applicant's arguments with respect to claim 27 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Claims 1, 3, 4, 5, 18, 20, 21, 23, 24, 25, 31, 32, 33, 34, 35, 40, and 41 are in condition for allowance because the claim is free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

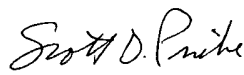
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader, SPE - Art Unit 1635, can be reached at (703) 308-0447.

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Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman
Patent Examiner, Group 1635


SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER